# Clinical trials of Drug eluting stent for coronary artery disease in diabetic patients

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## 1 drug-eluting stents

| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| **paclitaxel eluting stent vs bare-metal stent** | | | |
| TAXUS II (diabetics) , 2003 *unpublished*<br>n=37/41<br>follow-up: 12 months | TAXUS<br>versus<br>NIR stent | Diabetic patients with stable or unstable AP, silent ischaemia; single de novo target lesion with estimatedstenosis >50% and <99% , | Parallel groups<br>double-blind<br>Europe |
| TAXUS IV (diabetics) , 2005<br>[NCT00292474]<br>n=155/163<br>follow-up: 9 months | TAXUS<br>versus<br>EXPRESS | Diabetic patients with stable or unstable AP, provokable ischaemia with a single, previously untreated coronary-artery stenosis (vessel diameter, 2.5 to 3.75 mm; lesion length, 10 to 28 mm) | Parallel groups<br>double-blind<br>United States |
| TAXUS V (diabetics) , 2005<br>n=178/171<br>follow-up: 9 months | TAXUS<br>versus<br>BMS | Diabetic patients with stable or unstable AP, silent ischaemia with complex or previously unstudied lesions (requiring 2.25-mm, 4.0-mm, and/or multiple stents) | Parallel groups<br>double-blind<br>United States |
| TAXUS VI (diabetics) , 2005<br>[NCT00297804]<br>n=39/50<br>follow-up: 9 months | TAXUS<br>versus<br>Express2 stent | Diabetic patients with stable or unstable AP, silent ischaemia with long, complex coronary artery lesions | Parallel groups<br>double-blind<br>Europe |
| **sirolimus eluting stent vs bare-metal stent** | | | |
| DECODE , 2005 *unpublished*<br>[NCT00489164]<br>n=54/29<br>follow-up: 1 year | CYPHER (Up to 3 stents per patient were allowed)<br>versus<br>Bx VELOCITY (Up to 3 stents per patient were allowed) | Stable or unstable angina in diabetic patients with with up to 2 de novo lesions in up to 2 native coronary vessels | Parallel groups<br>open<br>US, Asia/Pacific |
| DESSERT , 2008<br>n=75/75<br>follow-up: 12 months | Cypher andCypher Select<br>versus<br>Sonic (Cordis) | de novo lesions of diabetic patients treated with insulin and/or oral antidiabetics for >3 months | Parallel groups<br>single-blind<br>Italy |
| DIABETES , 2005<br>n=80/80<br>follow-up: 9 months | Cypher<br>versus<br>Bx Velocity/Sonic | de novo lesions in native coronary arteriesin 1, 2, or 3 native vessels with symptoms or objective evidence of ischemia; vessel size smaller than 4.0 mm | Parallel groups<br>open<br>Spanish |
| Ravel (diabetics) , 2004<br>n=19/25<br>follow-up: 6 months | coated Bx velocity<br>versus<br>Bx VELOCITY | sub groups of diabetic patients with de novo native coronary arterylesions 2.5 to 3.5 mm in diameter by visualassessment that could be covered by an 18-mm stent | Parallel groups<br>NA<br>Europe |

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| SES-SMARt (diabetics) , 2005<br>n=29/45<br>follow-up: 8 months | Cypher<br>versus<br>Bx Sonic | Diabetic patients with de novo target lesion <=2.75 mm in diameter in a native coronary artery that could be completely covered by a single stent (maximum length 33 mm) | Parallel groups<br>single-blind<br>Italy |
| SIRIUS (diabetics) , 2003<br>n=131/148<br>follow-up: 12 months | SES<br>versus<br>BMS | sub group of diabetics patients of SIRIUS study | Parallel groups<br>double-blind<br>US |
| **CoStar stent vs paclitaxel eluting stent** | | | |
| COSTAR II diabetic (sub group) , 2008<br>n=271/271<br>follow-up: 8 months | CoStar stent (PES)<br>versus<br>Taxus stent (PES) | patients with de novo single- or multivessel coronary disease | Parallel groups<br>open |
| **paclitaxel eluting balloon vs paclitaxel eluting stent** | | | |
| PEPCAD IV *ongoing*<br>[NCT00462631]<br>n=NA<br>follow-up: | Paclitaxel-eluting PTCA-balloon dilation (SeQuentTM Please) followed by cobalt-chromium stent (CoroflexTM Blue) deployment<br>versus<br>Taxus Libert | patients with diabetes mellitus | open |
| **sirolimus eluting stent vs paclitaxel eluting stent** | | | |
| DES-DIABETES , 2008<br>n=200/200<br>follow-up: 9 months (1 year) | sirolimus-eluting stent<br>versus<br>paclitaxel-elutingstent | diabetic patients with angina pectoris and/or a positive stress test and a native coronary lesion | Factorial plan<br>open<br>Korea |
| ISAR-DIABETES , 2005<br>n=125/125<br>follow-up: 9 months | Taxus<br>versus<br>Cypher | Diabetic patients. AP or positive stress, no AMI with clinically significant angiographic stenosis in a native coronary vessel | Parallel groups<br>open<br>Germany |
| Kim , 2008<br>n=85/84<br>follow-up: 6 months | Cypher<br>versus<br>Taxus | Korean diabetic patients with high-grade de novo coronary lesions (stenosis of>70 percent of the luminal diameter) requiring <3 stents | Parallel groups<br>open<br>Korea |
| REALITY (diabetics) , 2006 *unpublished*<br>n=187/192<br>follow-up: 12 months | SES<br>versus<br>PES | - | Parallel groups<br>open<br>worldwide |
| SIRTAX diabetics , 2005<br>[NCT00297661]<br>n=108/93<br>follow-up: 12 months | Cypher<br>versus<br>Taxus | Sub groups of diabetics patients with either stable angina or an acute coronary syndrome | Parallel groups<br>single-blind<br>Switzerland |
| TAxi (diabetics) , 3000 *unpublished*<br>n=33/36<br>follow-up: 12 months | SES<br>versus<br>PES | - | Parallel groups<br>open<br>Switzerland |

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| Trial | Treatments | Patients | Trials design and methods |
|---|---|---|---|
| Tomai , 2008<br>n=60/60<br>follow-up: 8 months | sirolimus-eluting stent<br>versus<br>paclitaxel-eluting stent | diabetic patient with multiple de novo<br>coronary artery lesions | Cross over<br>NA<br>Italy |
| Lipsia-Yukon-DM *ongoing*<br>[NCT00368953]<br>n=NA<br>follow-up: 9 months | Yukon Choice stent system<br>versus<br>Taxus Libert stent system | Patients With Diabetes Mellitus | |
| **paclitaxel eluting stent vs sirolimus eluting stent** | | | |
| ISAR-test (diabetics) , 2006<br>n=73/58<br>follow-up: 9 months | Taxus<br>versus<br>rapamycin stent | diabetics patients with de novo lesions in<br>native coronary vessels, excluding the left<br>main trunk | Parallel groups<br>open<br>germany |
| **zotarolimus eluting stent vs sirolimus eluting stent** | | | |
| DIABEDES IV *ongoing*<br>[NCT00552994]<br>n=NA<br>follow-up: | Cypher select plus<br>versus<br>Xience V | diabetic patients | |

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**Tomai, 2008:**
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# 2 About TrialResults-center.org

TrialResults-center is an innovative knowledge database that collects the results of RCTs and provides dynamic interactive systematic reviews and meta-analysis in the field of all major heart and vessels diseases.

The TrialResults-center database provides a unique view of the treatment efficacy based on all data provided directly from clinical trial results, offering a valuable alternative to personal bibliographic search, published meta-analysis, etc. Furthermore, it would allow comparing easily the various concurrent therapeutic for the same clinical condition.

Rigorous meta-analysis method is used to populate TrialResults-center: widespread search of published and non published trials, study selection using pre-specified criteria, data extraction using standard form.

TrialResults-center is continually updated on a weekly basis. We continually search all new results (whatever their publication channel) and these news results are immediately added to the database with a maximum of 1 week.

TrialResults-center is non-profit and self-funded.